B BRAUN
SHARING EXPERTISE

November 18, 2021

Ethylene Oxide Commercial Sterilization Section 114 ICR Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

Re: Ethylene Oxide Section 114 Information Collection Request Response
B. Braun Medical Inc. Facility in Allentown, Pennsylvania

Dear Ms. Spells:

B. Braun Medical Inc. (B. Braun) operates a medical device manufacturing facility in Allentown, Pennsylvania (Facility). As part of its operations, B. Braun sterilizes medical devices using ethylene oxide (EtO). Therefore, the Facility is subject to 40 CFR Part 63, Subpart O (Ethylene Oxide Emissions Standards for Sterilization Facilities). On September 15, 2021, B. Braun received an Information Collection Request (ICR), dated September 13, 2021, from the U.S. Environmental Protection Agency (U.S. EPA) for information related to emissions of EtO from sterilization.

B. Braun is submitting two separate ICR responses to U.S. EPA pursuant to the Instructions Document: a confidential business information (CBI) submittal with associated CBI and non-CBI attachments, and a non-CBI submittal with associated non-CBI attachments. The response included with this letter is the non-CBI submittal.

B. Braun has made reasonable efforts to provide a complete response in the limited time provided. Certain information was unduly burdensome to obtain within the time constraints of this request. B. Braun's responses to the ICR are also provided subject to certain objections. First, to the extent that the ICR seeks information that is protected by the attorney-client privilege or attorney work product doctrine, B. Braun objects to any request for such information and has not provided that information in either submittal. Additionally, B. Braun objects to the extent the ICR seeks information not reasonably required for or related to EPA's proposed rulemaking on EtO. Accordingly, B. Braun objects to the request for information on alternative sterilization methods and other information determined to be not relevant to 40 CFR Part 63, Subpart O as authorized under the Clean Air Act.

Due to the limitations and restrictions of the ICR response workbook, B. Braun is attaching this letter in order to provide additional information regarding several responses to the ICR. The additional information is organized in bulleted lists below according to the tab and field of the workbook.

Facility Details Tab

- *A-23 and 24:* B. Braun currently operates pursuant to State Only Operating Permit (SOOP) No. 39-00055. As of the date of this submittal, B. Braun has one construction permit that is currently open and not included within the SOOP. B. Braun has included the construction permit and associated application for this activity within this request. In 2020, B. Braun completed the voluntary installation of a catalytic oxidizer and peak shaver to further reduce emissions associated with B. Braun's medical instrument apparatus sterilization operations. B. Braun has included the construction permit application associated with the installation and operation of the catalytic oxidizer and peak shaver installation within this request. This construction permit for this activity has been rolled into the current SOOP.

- *A-40, 41, and 42:* Emissions at the Facility are reported on a tons per year basis to the Pennsylvania Department of Environmental Protection (PADEP) as Source IDs 101-108 and 110 (i.e., eight Sterilizers and the Aeration Room, respectively). The definition of fugitive emissions, as provided within the "Terms" tab of this ICR, does not reflect the definition of fugitive emissions mentioned by reference within 40 CFR Part 63, Subpart O (i.e., 40 CFR Part 63, Subpart A). B. Braun has provided emissions for stack and fugitive emissions under A-40 and A-41, respectively, as defined on the "Terms" Tab. As used in the ICR response, stack emissions represent the emissions reported to PADEP that have been routed through a control device, and fugitive emissions represent the emissions reported to PADEP that have not been routed through a control device (i.e., fugitive and uncontrolled rear exhaust emissions, as applicable). Because of the definitional differences in the term "fugitive emissions," the numbers provided do not match directly previously reported values.

- *A-43:* The 2020 average annual energy cost provided in this field represents the energy cost for the entire Facility. B. Braun does not measure energy consumption for sterilization specific processes.

- *A-44:* The Facility does not provide sterilization services as a contractor (i.e., all sterilized products are manufactured by B. Braun) and therefore, the Facility is unable to provide revenue directly related to sterilization services.

- *A-39.1:* The top 57% of items sterilized in 2020 by volume were analyzed for packaging materials to come up with corresponding usage percentages.

Room Area Tab

- *B-9:* Room area ventilation air flow values are averaged for the area and are taken from a recently conducted air flow study of the Facility. The air flow value provided for shipping and staging (Room Area 2-180) represents winter conditions. In summer, the average air flow in Room Area 2-180 is -10,950 cubic feet per minute (cfm).

Sterilizer Chambers Tab

- *Table 2:* Each of B. Braun's sterilizer units has the ability to complete various cycles of sterilization (i.e., Cycles 1 through 3). Although B. Braun utilizes other cycles, the vast majority of products sterilized at the Facility are processed under Cycle 1 or Cycle 3. The parameters for which U.S. EPA has requested information in Table 2 of the 'Sterilizer Chambers' tab may vary depending on which cycle is being performed. Therefore, B. Braun has listed each sterilizer twice in Table 2 to provide approximate ranges for operation and monitoring characteristics during Cycle 1 (i.e., deep vacuum) and Cycle 3 (i.e., shallow vacuum). In the event that an answer is the same for both Cycle 1 and Cycle 3, B. Braun has only filled out the corresponding Cycle 1 rows.

- *E-7*: The number of cycles provided represents calendar year 2020.

- *E-15:* B. Braun has provided $126,000.00 as the annual cost of nitrogen washes. This is the total annual cost for nitrogen supply and does not represent the annual individual sterilizer nitrogen wash cost.

- *E-108 through 110.1:* Stack S23 is permitted in B. Braun's SOOP as the Common Rear Sterilizer Exhaust Stack and represents the previously utilized uncontrolled chamber exhaust vent (CEV). While Stack S23 is included within the SOOP, it is not currently operational. B. Braun currently exhausts the CEV to the dry bed air cleaning device. Therefore, the stack is not included in this response.

Aeration Tab

- *F-14:* The aeration room and sample aeration room are held under constant negative pressure during operation of the Anguil system. Air flow sensors are used to ensure that pressure within the aeration room remains negative at all times. In the event that the Anguil system is not operational for any period of time, the doors to the aeration room are automatically locked out and cannot be opened.

- *F-19:* Leaks in the aeration rooms at the Facility do not result in emissions of EtO to the atmosphere as the aeration rooms are maintained under constant negative pressure. Therefore, B. Braun has not provided information within this field.

APCD Summary Tab

- *G-14:* The air pollution control device (APCD) maintenance cost provided for the Anguil system represents only the cost of annual preventative maintenance performed by the supplier and does not include additional costs for repair.

APCD Details

- *H-35 and 37:* The operating temperature provided represents the minimum operating temperature of the Anguil system as determined in the December 2020 performance test.

Miscellaneous Tab

- *J-3:* B. Braun does not consider water associated with the vacuum pump condensate that is sent to the Anguil system peak shaver to be wastewater. Therefore, B. Braun has not provided information within this field.

- *L-3:* B. Braun has qualified its products/product families for EtO residuals per the requirements of ISO 10993-7. There are numerous qualification packages, which are approximately 800 pages each. The packages are maintained in the Facility's document management system and are available upon request.

If you have any questions concerning this submittal, please contact me at (610) 596-2474 or eric.geder@bbraunusa.com.

Sincerely,
B. Braun Medical Inc.

Eric Geder, CSP
EHS&S Manager

cc: Christina Lynch, P.E. – ALL4 LLC